1. Submitter Information:

MAR 2 2 2002

K014240

1.1. Submitter:

Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
Twinsburg, OH 44087
Phone: (847) 463-2001
FAX: (847) 463-2011

1.2. Manufacturing Facility:

Hitachi Medical Corporation
Kashiwa Works
2-1 Shintoyohuta, Kashiwa
Kashiwa City
Chiba Prefecture, Japan

1.3. Contact:

Robert H. McCarthy

1.4. Date: December 15, 2001

2. Device Name

2.1.	***Classification Name:***	Computed Tomography System
	Classification Number:	90JAK
2.2.	***Trade/Proprietary Name:***	Pronto
2.3.	***Predicate Device:***	Philips Medical Systems Secura, K 991278

3. Device Description

3.1. Function

The Pronto is a computed tomography system consisting of a gantry, computer operator's console, patient table, high frequency x-ray generator and accessories. Computed tomography (CT) is a radiographic method that uses a computer to reconstruct an image of a cross sectional plane of an object. The Pronto system utilizes "Third Generation" geometry with the x-ray tube and x-ray detector mounted on a rotating frame. A fan beam of x-rays generated by an x-ray tube mounted in the gantry passes through the patient and is detected by a solid state x-ray detector. The rotating frame containing the x-ray tube and x-ray detector rotate concentrically

about the patient utilizing slip ring technology. As the x-ray tube and detector move around the patient, data is collected at multiple angles. A cross-sectional image is then reconstructed using the collected data by specialized high speed electronics. The reconstructed images can then be viewed on the computer workstation, printed on a printer or transferred to an archive or remote viewing station. The high voltage required for the x-ray tube is generated on the rotating frame with a high frequency transformer. The x-ray detector is similar in design to the predicate device. The computer workstation is PC based utilizing the latest Intel Pentium technology. The operating system is Windows NT.

4. Device Intended Use:

4.1. The intended use of the Pronto is to produce cross-sectional images of the body by using high-speed electronics to mathematically reconstruct axial slices using data produced by x-ray transmission data from the same axial plane taken at different angles. The system can then display, process and store the reconstructed slices.

5. Device Technological Characteristics:

5.1. The characteristics of the Pronto Computed Tomography System compare substantially with the Philips Medical Systems Secura predicate device, in both materials used, technology applied, and functional methodology. Differences of note do not affect safety and effectiveness of the device, intended use, or application methods. The device operates in a manner substantially equivalent to other cleared devices in this category, and performs as well as the predicate Secura.

5.2. Safety

The Pronto is a non-invasive device. It has been designed to comply with applicable safety standards and the applicable sections of 21CFR. An initial product report defined by 21CFR 1002.10 will be submitted prior to the first Pronto shipment.
The results of the hazard analysis indicate that the device is of minor level of concern as defined in the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2002

Mr. Robert McCarthy
Director of New Technology
Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
TWINSBURG OH 44087

Re: K014240
Trade/Device Name: Pronto
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: December 14, 2001
Received: December 26, 2001

Dear Mr. McCarthy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K014240

Device Name: Pronto

Indications for Use:

The intended use of the Pronto is to produce cross-sectional images of the body by using high-speed electronics to mathematically reconstruct axial slices using data produced by x-ray transmission data from the same axial plane taken at different angles. The system can then display, process and store the reconstructed slices.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seyer

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K014240

Prescription Use 1 OR Over-the-Counter Use _____